IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

Momenta Pharmaceuticals, Inc., Plaintiff, v. Mylan Pharmaceuticals, Inc., Mylan Inc., Viatris Inc., Mylan Teoranta, Natco Pharma Ltd., and Gland Pharma, Ltd., Defendants.	Civil Action No. 2:22-CV-750 **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Momenta Pharmaceuticals, Inc. ("Momenta"), for its Complaint against Defendants Mylan Pharmaceuticals, Inc. ("MPI"), Mylan Inc., Viatris Inc. ("Viatris"),[1] Mylan Teoranta, Natco Pharma Ltd. ("Natco"), and Gland Pharma, Ltd. ("Gland") (collectively, "Defendants"), hereby alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code. This action arises out of Defendants' manufacture, importation, and sale of generic glatiramer acetate products (herein after referred to as "Glatiramer Acetate Injection 20 mg/mL" and "Glatiramer Acetate Injection 40 mg/mL" or, collectively, "Mylan Glatiramer Acetate Products") made by Momenta's patented methods, prior to the expiration of United States Patent No. 8,859,489 ("the '489 patent", attached hereto as Exhibit 1) and United States Patent No. 9,395,374 ("the '374 patent", attached hereto as Exhibit 2).[2]

[1] MPI, Mylan Inc., and Viatris Inc. are collectively referred to hereinafter as "Mylan."
[2] The '489 patent and '374 patent are collectively referred to hereinafter as the "patents-in-suit."

THE PARTIES

2. Plaintiff Momenta is a Delaware corporation with a principal place of business at 1125 Trenton-Harbourton Road, Titusville, NJ 08560.

3. Momenta is a wholly owned subsidiary of Johnson & Johnson.

4. Upon information and belief, Defendant MPI is a corporation organized and existing under the laws of West Virginia, with a principal place of business at 781 Chestnut Ridge, Morgantown, West Virginia 26505. MPI is registered with the Pennsylvania Department of State, as a business operating in Pennsylvania as Entity No. 232038. (Ex. 3 – Pennsylvania Department of State Business Entity Report for MPI). Upon information and belief, MPI has appointed CT Corporation System of Dauphin County, Pennsylvania, as its registered agent for service of process in Pennsylvania. (*Id.*) MPI is registered with the Pennsylvania Department of Health Drug, Device and Cosmetic Program as a "Distributor of Prescription Drugs, Controlled Substances and/or Seller/Distributor of Medical Gases" under Certificate No. 3000008447. (Ex. 4 – Pennsylvania Department of Health Public Lookup (https://apps.health.pa.gov/ddc/DDCPublicLookup.asp); Ex. 5 – Pa. Dep. of State Certificate Type Description).

5. Upon information and belief, Defendant Mylan Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with a principal place of business at 1000 Mylan Boulevard, Canonsburg, PA, 15317. (Ex. 6 – Mylan Inc. Form S-4 2018).

6. Upon information and belief, Mylan Teoranta is a corporation organized and existing under the laws of Ireland, with a principal place of business at Kilrow East, Inverin, Co. Galway, Ireland. (Ex. 7 – Viatris Ireland Contact Page (https://www.viatris.com/en-ie/lm/ireland/contact-us); Ex. 8 – Bladder Smart Page (https://www.bladdersmart.org/en/terms-and-conditions)). Upon information and belief, Mylan Teoranta trades under the name Mylan

Institutional. (*See, e.g.*, Ex. 9 – Mylan Name Change Letter (http://www.oncoscan.ro/documente/autorizatii/Mylanlegalnamechange-Cystistat.pdf); Ex. 10 – Irish Times Article (https://www.irishtimes.com/business/health-pharma/court-refuses-injunctions-in-pharma-patent-case-1.3521362); Ex. 8 – Bladder Smart Page (https://www.bladdersmart.org/en/terms-and-conditions)).

7. Upon information and belief, Defendant Viatris is a corporation organized and existing under the laws of the state of Delaware, with a principal place of business at 1000 Mylan Blvd., Canonsburg, PA 15317. (Ex. 11 – Viatris Inc. Form 10-K, 2021, at 1). Viatris is registered with the Pennsylvania Department of State, as a business operating in Pennsylvania as Entity No. 7166717. (Ex. 12 – Pennsylvania Department of State Business Entity Report for Viatris).

8. Upon information and belief, MPI is a wholly owned subsidiary of Mylan Inc., which is a wholly owned subsidiary of Viatris. (Ex. 11 – Viatris Inc. Form 10-K, 2022, at 165, 167; *see Merck Sharp & Dohme B.V. et al. v. Mylan Pharms. Inc. et al.*, No. 1:20-cv-00061-JPB (N.D. W. Va.), ECF No. 20, ¶ 7).

9. Upon information and belief, Defendant Mylan Teoranta is a wholly owned subsidiary of Viatris, and is an affiliate of MPI. (Ex. 11 – Viatris Inc. Form 10-K, 2022, at 163).

10. Upon information and belief, Defendant Natco is a corporation organized and existing under the laws of India, with a registered office and corporate headquarters at Natco House, Road No. 2, Banjara Hills, Hyderabad 500 034, India. Natco is a pharmaceutical manufacturer with active pharmaceutical ingredient facilities, finished dosage facilities, and a research center, all located in India. (Ex. 13 – Rao Declaration).

11. Upon information and belief, Defendant Gland Pharma Limited ("Gland") is an Indian corporation with a registered office at 6-3-865/1/2 Greenland Apartments, Ameerpet,

Hyderabad, 500 016, India. Gland is a pharmaceutical manufacturer whose activities include active pharmaceutical ingredient manufacture, formulation development, and finished dosage manufacturing. (Ex. 14 – Gland Brochure).

12. Upon information and belief, Defendants, themselves and through their subsidiaries, affiliates, and agents, develop, manufacture, import, market, distribute, and/or sell generic pharmaceutical versions of branded products for sale and use throughout the United States, including in this District.

13. Upon information and belief, as discussed in more detail below, Defendants are agents of each other and/or work in concert with respect to the development, manufacture, regulatory approval, marketing, import, sale, and/or distribution of pharmaceutical products, including the Mylan Glatiramer Acetate Products, throughout the United States, including in this District.

14. Upon information and belief, Defendants developed, manufacture, market, sell, import, and/or distribute the Mylan Glatiramer Acetate Products, including in this District.

THE PATENTS-IN-SUIT

15. The ’489 patent, entitled “Water-Mediated Control of Depolymerization Step of Glatiramer Acetate Synthesis,” was duly and legally issued by the United States Patent and Trademark Office (“USPTO”) on October 14, 2014, naming as inventors Claire Coleman, John Schaeck, and Alicia Thompson. A copy of the ’489 patent is attached hereto as Exhibit 1.

16. The ’374 patent, entitled “Analysis of Amino Acid Copolymer Compositions,” was duly and legally issued by the United States Patent and Trademark Office on July 19, 2016, naming as inventors Xiangping Zhu, Zachary Shriver, Yanjie Jiang, Corinne Bauer, James Eric Anderson, and Peter James Ahern. A copy of the ’374 patent is attached hereto as Exhibit 2.

17. Momenta is the exclusive and lawful owner of all rights, title, and interest in both of the patents-in-suit, and has the right to bring this suit and to recover damages for any current or past infringement of both of the patents-in-suit.

18. The patents-in-suit are directed to commercial manufacturing methods invented by Momenta in their development of Glatopa® (glatiramer acetate injection), a glatiramer acetate product used in the treatment of multiple sclerosis and approved by the United States Food & Drug Administration ("FDA").

19. The '374 patent discloses and claims novel methods for manufacturing pharmaceutical compositions comprising glatiramer acetate. The methods include steps for controlling pyro-glutamate content by measuring it and processing a copolymer to produce a pharmaceutical composition comprising glatiramer acetate only if the measured pyro-glutamate content of the copolymer is within a specific range (2000–7000 parts per million (ppm)). The inventors of the '374 patent discovered that controlling the pyro-glutamate content during the manufacture of glatiramer acetate controls the quality of the glatiramer acetate produced, and the '374 patent describes and claims novel manufacturing methods that utilize analytical process steps that enable controlling the pyro-glutamate levels as part of the manufacturing process.

20. The '489 patent discloses and claims novel methods for preparing compositions comprising purified glatiramer acetate in which the depolymerization step of the glatiramer acetate preparation process is controlled by ensuring the presence of water during that step in an amount such that the pyro-glutamic acid ("pyro-Glu")[3] levels of the resulting glatiramer acetate are in a specific range (2000–7000 parts per million (ppm)).

[3] Pyro-glutamate is the anionic form of pyro-glutamic acid (*i.e.*, pyro-glutamate lacks a hydrogen on its carboxyl group that is present in pyro-glutamic acid) and the '374 and '489 Patents refer to

BACKGROUND

21. Multiple sclerosis is a chronic inflammatory disease of the central nervous system that affects more than 2 million individuals globally and approximately 400,000 individuals in the United States. (*See* Ex. 57 – Bell 2018, at 2). Physicians have combatted the disease for decades, but a silver bullet has eluded discovery: while there are numerous treatment options to manage symptoms or slow disease progression, there is no cure. *Id.*

22. One of these treatment options is glatiramer acetate. Also known as copolymer-1, glatiramer acetate is a heterogeneous mixture of peptides comprising four amino acids and is similar in structure to the myelin basic protein, which is thought to play an important role in the pathogenesis of multiple sclerosis. *Id.* at 2. Teva was the first to seek approval in the United States to market glatiramer acetate as a treatment for multiple sclerosis.

Teva's Copaxone® (glatiramer acetate injection) Products

23. Teva's New Drug Application ("NDA") for glatiramer acetate was approved by the FDA in 1996, and Teva began selling the drug under the trade name Copaxone® (glatiramer acetate injection) in the United States in 1997.[4] For almost twenty years, Copaxone® (glatiramer acetate injection) was the only glatiramer acetate product available on the market. Copaxone® (glatiramer acetate injection), sold in a once-daily 20 mg/mL formulation and a three-times weekly 40 mg/mL formulation, is one of the leading products marketed to treat relapsing forms of multiple sclerosis, and is frequently prescribed as a first-line therapy in newly diagnosed patients.

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pyro-glutamate and pyro-glutamic acid interchangeably. (*See* Ex. 2 – '374 Patent, at 1:35–45 (referring to both as pyro-Glu); Ex. 1 – '489 Patent, at Example 2 (identifying the "peak corresponding to the pyro-glutamate moiety" in measuring "pyro-Glu concentration").

[4] *See* discussion of Teva's NDA at *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, 876 F. Supp. 2d 295, 306–07 (S.D.N.Y. 2012) (subsequent history omitted).

24. Copaxone® (glatiramer acetate injection) comprises acetate salts of synthetic polypeptides made up of four naturally occurring amino acids: L-glutamic acid, L-alanine, L-tyrosine, and L-lysine, with a reported average molar fraction of 0.141, 0.427, 0.095, and 0.338, respectively. (*See* Ex. 15 – Copaxone Package Insert, at 3). Other than average molecular weight and amino acid composition, which are specified on the FDA-approved label for Copaxone® (glatiramer acetate injection), the label and other available literature for Copaxone® (glatiramer acetate injection) have historically provided no detailed information about the physicochemical characteristics of the product. (*See* Ex. 16 – FDA Response, at 25).

25. Glatiramer acetate is generally prepared in three discrete steps.[5] (Ex. 16 – FDA Response, at 13 n.44). In a first step, activated forms of the four constituent amino acids are combined and polymerized in the presence of a polymerization initiator, forming an intermediate copolymer (*i.e.*, a chain of the four constituent amino acids). During this initial polymerization step, certain of the functional groups of the amino acids must be shielded by protecting groups to prevent undesirable side reactions. In a second step, the intermediate copolymer formed in the first step is partially depolymerized and deprotected (*i.e.*, the chain is broken into smaller pieces, and one of the protecting groups is removed). A third step completes the deprotection of the amino acid functional groups and purifies the resulting product, glatiramer acetate. This synthetic process results in a complex, heterogeneous product with inherent variability in the composition of the synthetic polypeptides formed, which vary in amino acid sequence and polypeptide length, as well as variability in the polypeptide composition of manufacturing batches. (*See* Ex. 16 – FDA

[5] The specific process by which Teva makes and manufactures Copaxone® (glatiramer acetate injection) is proprietary and non-public. (*See* Ex. 17 – (https://www.copaxonehcp.com/about-copaxone/manufacturing) ("Teva's controlled, ***proprietary manufacturing process*** and quality control system ensure batch-to-batch consistency." (emphasis added)); Ex. 16 – FDA Response, at 25).

Response, at 11). Copaxone® (glatiramer acetate injection) was the only glatiramer acetate product available on the market for almost twenty years, as the complexity of the product and the lack of understanding of the chemical structure of Copaxone® (glatiramer acetate injection) and structural signatures for key steps in manufacturing glatiramer acetate prevented development of a generic version of glatiramer acetate that would possess adequate sameness to Copaxone® (glatiramer acetate injection).

Momenta's Development of Glatopa® (glatiramer acetate injection)

26. Momenta was founded in 2001 and is a leader in the analysis, characterization, design, and preparation of complex pharmaceutical products. Momenta has developed innovative approaches to understand the relationship between a compound's chemical structure, its manufacturing process, and its biological function, even in the case of very complicated pharmaceutical products, and then has applied those understandings to prepare complex pharmaceutical products. Among other things, Momenta applies its innovative technology to the development of generic versions of non-biological complex drugs.

27. Momenta has developed and patented novel ways to manufacture complex pharmaceuticals. Momenta's patented methods were used to develop and gain regulatory approval from the FDA for the first generic version of Copaxone® (glatiramer acetate injection).

28. Glatopa® (glatiramer acetate injection) was developed and commercialized in collaboration with Sandoz, and was the first FDA-approved generic version of Copaxone® (glatiramer acetate injection).

29. Glatopa® (glatiramer acetate injection) 20 mg/mL is a therapeutically equivalent ("AP" rated) fully substitutable version of Teva's daily Copaxone® (glatiramer acetate injection) 20 mg/mL product. Glatopa® (glatiramer acetate injection) 40 mg/mL is an "AP" rated, fully

substitutable version of Teva's three-times-per-week Copaxone® (glatiramer acetate injection) 40 mg/mL product. Both Glatopa® (glatiramer acetate injection) 20 mg/mL and Glatopa® (glatiramer acetate injection) 40 mg/mL are indicated for the treatment of patients with relapsing forms of multiple sclerosis. (Ex. 18 – Glatopa® Package Insert).

30. The discovery of Momenta's patented inventions, which are described and claimed in the patents-in-suit, required years of intense laboratory work. Momenta began its research program seeking methods for the consistent and controlled preparation of glatiramer acetate equivalent to FDA-approved Copaxone® (glatiramer acetate injection) by no later than the beginning of 2006.

31. Momenta made the unexpected discovery that controlling the glatiramer acetate manufacturing process to produce a specific amino acid derivative (pyro-Glu) within a specific range, measuring the amount of pyro-Glu generated in the manufacturing process, and then selecting batches of glatiramer acetate for further processing based on that pyro-Glu content in that specific range, results in a replicable glatiramer acetate manufacturing process capable of achieving equivalence (*e.g.*, active pharmaceutical ingredient ("API") sameness) to the Copaxone® (glatiramer acetate injection) product.

32. Momenta also discovered that, unlike the prior art, the manufacturing process of glatiramer acetate could be improved such that generic glatiramer acetate manufacturing could be achieved by including water during the depolymerization step of the manufacturing process. Momenta unexpectedly discovered that the addition of water to the depolymerization step in the glatiramer acetate manufacturing process allowed for the reaction to occur in a controlled manner, resulting in the production of glatiramer acetate that consistently achieved levels of pyro-Glu in

the specific range necessary to conform to FDA-approved Copaxone® (glatiramer acetate injection).

33. Prior to the inventions described and claimed in the patents-in-suit, it was unknown that including water during the depolymerization step and controlling and measuring the pyro-Glu formation as a process step in the manufacture of glatiramer acetate, would result in consistent production of glatiramer acetate API for making a pharmaceutical product equivalent to Copaxone® (glatiramer acetate injection).

34. After Momenta began research in the area, it entered into a collaboration and license agreement with Sandoz in 2007 regarding the development of a generic glatiramer acetate drug product. Using the methods of manufacture claimed in the patents-in-suit, Momenta worked in collaboration with Sandoz to develop and commercialize Glatopa® (glatiramer acetate injection), a generic form of Teva's Copaxone® (glatiramer acetate injection).

35. The Abbreviated New Drug Application ("ANDA") for Glatopa® (glatiramer acetate injection) 20 mg/mL, ANDA 090218, was submitted to the FDA in 2007.

36. In order to be approved by the FDA, a drug product described in an ANDA must be bioequivalent to the reference listed drug ("RLD"), and equivalent in dosage form, strength, route of administration, quality, performance characteristics, and intended use. Section 505(j)(2)(A)(iv) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) (requiring that an ANDA provide information to show that the new drug is bioequivalent); 21 C.F.R. § 314.94(a)(6) (requiring that an ANDA provide information to show that the route of administration, dosage form, and strength of the drug product is the same as the RLD); 21 C.F.R. § 320.21(b) (requiring that an ANDA provide evidence of bioequivalence).

37. In order to be approved by the FDA, the active ingredient(s) in an ANDA product must be "the same as" the reference listed drug product's active ingredient(s). 21 C.F.R. § 314.94(a)(5). Thus, generic applicants must demonstrate to the FDA's satisfaction that the active pharmaceutical ingredient contained in their proposed generic product is "the same as" the active ingredient in the reference listed drug product.

38. As part of the FDA approval process for Glatopa® (glatiramer acetate injection) 20 mg/mL, the FDA required demonstration that the proposed generic glatiramer acetate active ingredient synthesized by Momenta's manufacturing processes resulted in glatiramer acetate that is the same as the active ingredient in Copaxone® (glatiramer acetate injection), and sufficient information to show that the proposed generic drug product was bioequivalent to Copaxone® (glatiramer acetate injection).

39. While the Glatopa® (glatiramer acetate injection) 20 mg/mL ANDA was pending, Teva sought to block FDA approval of any ANDA for a generic glatiramer acetate product through a series of Citizen Petitions, arguing, among other things, that their Copaxone® (glatiramer acetate injection) product was too complex to be replicated and requesting heightened sameness criteria. (*See* Ex. 16 – FDA Response, at 1–2). As Teva explained in its Citizen Petitions and the FDA acknowledged, the chemical complexity of glatiramer acetate rendered it incredibly difficult to evaluate whether a generic glatiramer acetate was the same as the active ingredient of Copaxone® (glatiramer acetate injection), and equally difficult to ensure that the manufacturing process for generic glatiramer acetate would reliably result in glatiramer acetate that was the same as Copaxone® (glatiramer acetate injection). *See id.* at 1–3, 11. Indeed, Teva argued that no ANDA applicant could demonstrate "that the active ingredient in the purported generic is the same as that

in [Copaxone® (glatiramer acetate injection)]." (Ex. 23 – Teva First Citizen Petition, at 17–18). As Teva explained (*see id.*):

> The unique complexity of Copaxone® makes such a demonstration impossible. Unlike most small-molecule drugs, the active ingredient in Copaxone®—glatiramer acetate—is a complex mixture of polypeptides that contains a huge, perhaps incalculable number of epitopes. At this time, even the most sophisticated chemical analytical tests, including multidimensional analysis, cannot identify and characterize each of the active amino acid sequences that make up glatiramer acetate.

40. Yet Momenta discovered methods that Teva said were "impossible": methods that reliably produced glatiramer acetate that was the same as the active ingredient in Teva's Copaxone® (glatiramer acetate injection). In doing so, Momenta submitted to the FDA extensive physiochemical, biological, and immunological characterization via *more than 60 methods*. (*See* Ex. 57 – Bell 2018, at 3). Through its extensive characterization of the glatiramer acetate in Glatopa® and in Copaxone® (glatiramer acetate injection), Momenta discovered several "structural signatures" for glatiramer acetate which could be incorporated into manufacturing process steps to ensure that the resulting product was the same as the active ingredient in Copaxone® (glatiramer acetate injection). Identifying these structural signatures was not easy. Because of the "inherent variability" of glatiramer acetate, (*see* Ex. 16 – FDA Response, at 11), even aspects of the substance that are said to be "conserved" from batch to batch nonetheless vary to some degree. *Id.* at 11 n.38.

41. One of these structural signatures discovered by Momenta was the pyro-Glu concentration of glatiramer acetate. As discussed in more detail below, Momenta discovered that the pyro-Glu concentration served as an important structural signature for the depolymerization step of the manufacturing process for glatiramer acetate, and the FDA agreed. Therefore, along with other structural signatures for the manufacturing process as a whole, comparison of pyro-Glu

concentration in batches of generic glatiramer acetate with the pyro-Glu concentration of Copaxone® (glatiramer acetate injection) was important to show "sameness" between generic glatiramer acetate and Copaxone® (glatiramer acetate injection). Indeed, Momenta demonstrated to the FDA that the pyro-Glu concentration of the glatiramer acetate in Glatopa® (glatiramer acetate injection) matched that of the glatiramer acetate in Copaxone® (glatiramer acetate injection).

42. After Momenta submitted this and other evidence, once-daily Glatopa® (glatiramer acetate injection) 20 mg/mL product was approved in April 2015 as the first generic glatiramer acetate product in the United States. On April 16, 2015, the same day that the FDA approved the Glatopa® (glatiramer acetate injection) 20 mg/mL ANDA, the FDA denied all eight of Teva's Citizen Petitions in a public response setting forth the FDA's approach to the review and evaluation of proposed glatiramer acetate ANDAs referencing Teva's Copaxone® (glatiramer acetate injection). *See id.* The FDA required, among other things, that generic glatiramer acetate applicants demonstrate equivalence of the "[s]tructural signatures for polymerization and depolymerization" between any proposed generic glatiramer acetate and the active ingredient of Copaxone® (glatiramer acetate injection), one of these structural signatures for the depolymerization step being, as Momenta had discovered, the concentration of pyro-Glu. *Id.* at 18 n.61, 21, 28. The FDA later published draft guidance providing "recommendations for the development of generic product of glatiramer acetate injection." (*See* Ex. 19 – Draft FDA Guidance at 1). The draft guidance is consistent with the approach described in the CP Response and directs readers to the CP Response for "more detailed discussion." *Id.* at 1 n.1.[6]

[6] The FDA issued the CP Response and Draft Guidance after the filing dates for the '489 and '374 Patents, and after the date the '489 Patent was issued. (*Compare* Ex. 1 – '489 Patent, *and* Ex. 2 – '374 Patent, *with* Ex. 16 – FDA CP Response, *and* Ex. 19 – FDA Draft Guidance).

43. The ANDA for Glatopa® (glatiramer acetate injection) 40 mg/mL, ANDA 206921, covering a three-times-weekly glatiramer acetate formulation at a dose of 40 mg/mL, was submitted to the FDA on February 14, 2014. On February 13, 2018, the FDA approved the ANDA for Glatopa® (glatiramer acetate injection) 40 mg/mL.

Mylan's Glatiramer Acetate Product

44. The accused products in this litigation are generic glatiramer acetate products. Upon information and belief, MPI filed ANDAs for Glatiramer Acetate Injection 20 mg/mL and 40 mg/mL, generic versions of Teva's Copaxone® (glatiramer acetate injection) Products. (Ex. 20 – ANDA 091646 Approval Letter; Ex. 21 ANDA 206936 approval letter). MPI filed ANDA 091646 for a generic version of Copaxone® (glatiramer acetate injection) 20 mg/mL on June 29, 2009. (*See Teva Pharms.*, 876 F. Supp. 2d at 307–08; Ex. 22 – 2009.09.14 Press Release; Ex. 20 – ANDA 091646 approval letter). Mylan Inc. announced that MPI's ANDA 091646 for the 20 mg/mL form of its generic glatiramer acetate product was accepted for filing by the FDA on September 14, 2009. (Ex. 22 – 2009.09.14 Press Release).

45. MPI filed ANDA 206936 for a generic version of Copaxone® (glatiramer acetate injection) 40 mg/mL, which was accepted for review by the FDA on February 12, 2014. (Ex. 24 – 2014.08.28 Press Release; Ex. 21 – ANDA 206936 approval letter). Mylan Inc. announced that its ANDA for the 40 mg/mL version was accepted for filing on August 28, 2014. (Ex. 24 – 2014.08.28 Press Release).

46. On October 3, 2017, Mylan N.V. (now Viatris, as discussed below) announced that both of its glatiramer acetate ANDAs had received approval by the FDA. (Ex. 25 – 2017.10.03 Mylan Press Release).

47. On October 4, 2017, Mylan N.V. (now Viatris, as discussed below) announced that it had begun shipping Glatiramer Acetate Injection 20 mg/mL and 40 mg/mL to customers in the United States. (Ex. 26 – 2017.10.04 Mylan Press Release).

48. Upon information and belief, Mylan imports, imports for sale, and sells after importation, glatiramer acetate products containing glatiramer acetate supplied by Natco and/or Gland and made, produced, and/or processed under, or by means of, processes that infringe the patents-in-suit.

49. Mylan Inc. publicly announced in 2008 that it has an agreement with Natco for Natco to provide glatiramer acetate API for Mylan's Glatiramer Acetate Products in the U.S. market. (Ex. 27 – 2008.06.10 Mylan Press Release; Ex. 29 – Hindu Article; Ex. 45 – Money Control News Article Regarding Natco).

50. Upon information and belief, Natco manufactures, sells for importation, imports, and/or sells after importation glatiramer acetate API, and products containing the same, made, produced, and/or processed under, or by means of, processes that infringe the patents-in-suit.

51. Natco manufactures a number of pharmaceutical products, and is registered with the FDA. (Ex. 28 – Natco Pharma FDA Registration).

52. Mylan Inc. entered into a license and supply agreement with Natco, which granted Mylan Inc. exclusive distribution rights for glatiramer acetate prefilled syringes in the United States and all major markets in Europe, Australia, New Zealand, Japan, and Canada. (Ex. 27 – 2008.06.10 Mylan Press Release). The agreement also includes an option to potentially expand into additional territories. *Id.*

53. Upon information and belief, pursuant to the license and supply agreement with Mylan Inc., Natco is working with Mylan to manufacture glatiramer acetate for the U.S. market

and is importing and/or selling for importation into the United States glatiramer acetate to Mylan. A June 19, 2015, article stated as follows:

> A senior official of Natco told PTI that they have submitted all the information to [the] FDA with regard to the generic version of Copaxone (Glatiramer Acetate) which is used in the treatment of relapsing-remitting multiple sclerosis. "We have done everything from our side. Once approval comes, we are ready to launch the product. We manufacture the drug and Mylan will market it," the official said.

(Ex. 29 – Hindu Article).

54. On October 5, 2017, Natco announced that "its marketing partner Mylan N.V., has launched in the U.S the first Glatiramer Acetate Injection 40 mg/mL … as well as Glatiramer Acetate Injection 20 mg/mL." (Ex. 30 – 2017.10.05 Natco Press Release). In November 2019, Mylan N.V. and Pfizer Inc. announced the merger of Mylan and Upjohn, a division of Pfizer, and the renaming of the newly formed company as Viatris Inc. (Ex. 31 – 2019.11.12 Mylan press release). The merger was completed a year later, in November 2020. (Ex. 32 – 2020.11.16 Pfizer Press Release).

55. Today, Viatris markets and/or advertises Mylan's Glatiramer Acetate Products via the website www.glatirameracetate.com. (Ex. 33 – Viatris Glatiramer Acetate Website). For example, Viatris advertises a "Viatris Advocate" service that is a "patient support program to help [patients] access [glatiramer acetate] therapy as soon as possible." (Ex. 34 – Viatris Advocate Brochure). Viatris also offers, *e.g.*, a co-pay assistance program that allows patients' "co-pay[s] for VIATRIS' Glatiramer Acetate Injection [to be] as low as $0 a month." *Id.*

56. The logo used to market Mylan's Glatiramer Acetate Products is a registered trademark of "Mylan Pharmaceuticals Inc., a Viatris Company." (Ex. 33 – Viatris Glatiramer Acetate Website). To register that trademark, upon information and belief, MPI certified to the

United States Patent and Trademark Office that it had used or intended to use the trademark in commerce. *See, e.g.*, 15 U.S.C. § 1051.

57. Upon information and belief, glatiramer acetate manufactured by Natco has been imported into the United States. Upon information and belief, Natco, working with Mylan, has exported glatiramer acetate products from India, for commercial sale of glatiramer acetate products in the United States. (Ex. 35 – *Teva Pharms. USA, Inc. et al. v. Mylan Pharms. Inc., et al.*, 1:14-cv-01278 (D. Del.), ECF No. 1 at ¶ 37).

58. International shipping documents reveal that Natco has shipped glatiramer acetate products from India to Mylan in the United States. For example, those documents reveal that Natco has repeatedly shipped glatiramer acetate products to Kelly Jo Cox, an MPI employee, in Philadelphia, Pennsylvania. (Ex. 36 – 2018.12.06 Bill of Lading; Ex. 59 – Customs Ruling; *see also* Ex. 60 – 2018.05.09 Bill of Lading; Ex. 61 – 2018.01.02 Bill of Lading). Natco has also shipped glatiramer acetate products to MPI in Atlanta, Georgia. (Ex. 62 – 2021.09.28 Bill of Lading).

59. Upon information and belief, glatiramer acetate products manufactured by Natco have also been shipped to Mylan Teoranta in Ireland, which in turn has shipped glatiramer acetate products to MPI in the United States. (Ex. 63 – 2021.09.30 Bill of Lading; Ex. 37 – Mylan Teoranta Shipping Records).

60. Upon information and belief, Mylan Teoranta manufactures Mylan Glatiramer Acetate Products, made by a process that infringes the patents-in-suit, for distribution and sale by MPI throughout the United States and in this judicial District. The approved label for Mylan's 40

mg/mL Glatiramer Acetate Injection states that it is manufactured by Mylan Institutional[7] in Galway, Ireland for MPI. (Ex. 38 – Mylan 40mg/mL label, at 16). There have also been shipments of glatiramer acetate products from Mylan Teoranta in Ireland to MPI in the United States, involving quantities of product greater than that necessary for regulatory approval. (Ex. 37 – Mylan Teoranta Shipping Records).

61. Upon information and belief, Mylan Teoranta is a subsidiary of Viatris. (Ex. 11 – Viatris Form 10-K 2022, at 163).

62. Upon information and belief, Mylan and/or Natco also sold for importation and/or imported glatiramer acetate products to prepare for the commercial launch of its Glatiramer Acetate Products, including engaging in activities not covered by the safe harbor of 35 U.S.C. § 271(e)(1). As noted above, there have been shipments of glatiramer acetate products from India to the United States following Mylan's receipt of regulatory approval in the United States and in amounts greater than necessary for regulatory approval. (*See* Ex. 36 – 2018.12.06 Bill of Lading; Ex. 59 – Customs Ruling; *see also* Ex. 60 – 2018.05.09 Bill of Lading; Ex. 61 – 2018.01.02 Bill of Lading; Ex. 62 – 2021.09.28 Bill of Lading).

63. Upon information and belief, Gland manufactures Mylan Glatiramer Acetate Products made by a process that infringes the patents-in-suit, for distribution and sale by MPI throughout the United States and in this judicial District. The approved label for Mylan's 20 mg/mL Glatiramer Acetate Injection states that it is manufactured by Gland in India. (Ex. 39 –

[7] Mylan Teoranta trades under the name Mylan Institutional, as discussed above. (*See e.g.*, Ex. 9 – Mylan Name Change Letter (http://www.oncoscan.ro/documente/autorizatii/Mylanlegalnamechange-Cystistat.pdf); Ex. 10 – (https://www.irishtimes.com/business/health-pharma/court-refuses-injunctions-in-pharma-patent-case-1.3521362); Ex. 8 – (https://www.bladdersmart.org/en/terms-and-conditions).)

Mylan 20mg/mL label, at 15). Upon information and belief, Gland provides fill-finish services to Mylan, manufacturing pre-filled syringes containing glatiramer acetate supplied by Natco.

64. Upon information and belief, Gland manufactures, sells for importation, and/or imports glatiramer acetate products made, produced, and/or processed under, or by means of, processes that infringe the patents-in-suit.

65. Gland manufactures a number of pharmaceutical products, and is registered with the FDA. (Ex. 14 – Gland Corporate Brochure).

66. Upon information and belief, both the 20 mg/mL and 40 mg/mL forms of the Mylan Glatiramer Acetate Product are believed to be made by a process that infringes the claims of the patents-in-suit.

67. Upon information and belief, in order for the FDA to have approved Defendants' manufacture of generic glatiramer acetate, Mylan along with Mylan Teoranta, Gland and Natco will have included in their process for manufacturing batches of glatiramer acetate for commercial sale: (1) a method of manufacturing glatiramer acetate containing 2000–7000 ppm pyro-Glu by water-mediated control of the depolymerization step, which method infringes the '489 Patent; and (2) a method of manufacturing glatiramer acetate containing 2000–7000 ppm pyro-Glu, which method controlled and measured the pyro-Glu level as part of the manufacturing process, and which infringes the '374 Patent.

68. Upon information and belief, Defendants have knowledge of both the '374 and '489 patents. Upon information and belief, Mylan has filed and/or has knowledge of Oppositions to several of Momenta's European patents in the same families as the '374 and '489 patents.

69. For example, on September 14, 2014, Generics [UK] Ltd. ("trading as Mylan") filed an opposition to Momenta's European Patent No. 2,277,050, which claims priority to the

same provisional applications to which the '374 patent claims priority and shares a common disclosure with the '374 patent. (*See* Ex. 54 – Generics Notice of Opposition).

70. In addition, upon information and belief, Mylan filed an Opposition to Momenta's European Patent No. 2,414,384 (the "'384 Patent"), which claims priority to the same provisional applications to which the '489 Patent claims priority and shares a common disclosure with the '489 Patent. Specifically, the '384 Patent has been opposed by an entity represented by Gill Jennings & Every LLP ("GJE"). (*See* Ex. 65 – Notice of Representation by GJE). GJE has represented Mylan in connection with the Opposition filed to the '050 Patent. (*See* Ex. 66 – GJE Notice of Appeal). Indeed, other filings in the Opposition proceedings for the '384 Patent have explicitly referred to Mylan's involvement in those proceedings. (*See* Ex. 67 – Synthon Reply, at ¶¶ 99, 124). In addition, Synthon B.V. filed an Opposition to the '384 Patent. (*See* Ex. 53 – Synthon Notice of Opposition). Upon information and belief, Mylan N.V. (now Viatris) partnered with Synthon B.V. to develop and/or market glatiramer acetate in Europe, and therefore Synthon and Mylan have worked in concert in, or at a minimum kept each other apprised of, their EU oppositions related to glatiramer acetate. (*See* Ex. 55 – 2017.10.05 Mylan Press Release; Ex. 56 – 2020.09.16 Mylan Press Release).

71. In addition, upon information and belief, Mylan has informed Mylan Teoranta, Natco, and Gland of the EU Opposition activity related to Momenta's European patents, given their joint development and/or commercialization of glatiramer acetate, and thus all Defendants have knowledge of the '374 Patent and '489 Patents families, which include the '374 Patent and the '489 Patent.

JURISDICTION AND VENUE

72. Momenta incorporates by reference paragraphs 1–71.

A. Subject Matter Jurisdiction

73. This is a civil action for infringement of two United States patents, arising under the Patent Laws of the United States, including 35 U.S.C. § 271 *et seq*..

74. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

B. Personal Jurisdiction

75. This Court has personal jurisdiction over Defendants because, as discussed below, Defendants reside in Pennsylvania, transact business in Pennsylvania, contract to supply services or things in Pennsylvania, have committed acts constituting patent infringement (or inducement thereof) in Pennsylvania, and/or have caused harm to Momenta in Pennsylvania.

76. Upon information and belief, Defendants work in concert with one another to make, use, offer to sell, and sell generic glatiramer acetate products throughout the United States, including in Pennsylvania.

77. Momenta receives royalties from the sale of Glatopa® (glatiramer acetate injection) products in the Commonwealth of Pennsylvania.

78. Upon information and belief, as a result of Defendants' marketing, selling, or offering for sale of the Mylan Glatiramer Acetate Products in the Commonwealth of Pennsylvania, Momenta has lost royalties and profit from the loss of sales of Glatopa® (glatiramer acetate injection) products and has been injured in the Commonwealth of Pennsylvania.

79. Upon information and belief, Defendants, either each alone and/or together with one another as affiliates and/or agents, have committed, or aided, abetted, actively induced,

contributed to, or participated in the commission of an act of patent infringement under 35 U.S.C. § 271(a)–(c) and/or (g) that has led and/or will lead to foreseeable harm and injury to Momenta in Pennsylvania.

Defendant Mylan

80. Upon information and belief, MPI is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in Pennsylvania and throughout the United States.

81. This Court has specific personal jurisdiction over MPI pursuant to due process and/or the Pennsylvania Long Arm Statute by virtue of the fact that, *inter alia*, MPI has committed or induced tortious acts of patent infringement under 35 U.S.C. § 271 in Pennsylvania, and intends a future course of conduct that includes committing or inducing acts of patent infringement in Pennsylvania. These acts have led and will lead to foreseeable harm and injury to Momenta in Pennsylvania.

82. For example, upon information and belief, MPI conducts business in Pennsylvania, by at least offering for sale, importing, and/or selling Mylan Glatiramer Acetate Products, which are made by the claimed inventions of the Patents-in-Suit, in Pennsylvania. For example, upon information and belief, MPI imports generic glatiramer acetate made by the claimed inventions of the Patents-in-Suit into Pennsylvania. (Ex. 52 –2018.12.29 Bill of Lading; Ex. 36 – 2018.12.06 Bill of Lading; Ex. 59 – Customs Ruling; *see also* Ex. 60 – 2018.05.09 Bill of Lading; Ex. 61 – 2018.01.02 Bill of Lading).

83. Upon information and belief, MPI conducts substantial business in the Commonwealth of Pennsylvania and this judicial District, including at least regularly doing and soliciting business at its Austin, Pennsylvania facilities, and engaging in persistent conduct and/or

deriving substantial revenue from goods and services provided to customers in the Commonwealth of Pennsylvania, including in the Western District of Pennsylvania.

84. Upon information and belief, MPI has previously actively litigated in this jurisdiction. *See, e.g.*, *Amgen Inc. v. Mylan Inc.*, No. 2-17-cv-01235 (W.D. Pa.).

85. Personal jurisdiction also exists over MPI because MPI has additional substantial, continuous and systematic contacts with Pennsylvania, including, among other things, registration as an entity doing business in Pennsylvania, employment of officers based in Pennsylvania, appointment of a registered agent in Pennsylvania for service of process, and registration as a manufacturer and wholesale distributor of drugs in Pennsylvania.

86. Upon information and belief, MPI is a wholly owned subsidiary of Mylan Inc., which exercises considerable control over MPI. *See Merck Sharp & Dohme B.V. et al. v. Mylan Pharms Inc. et al.*, No. 1:20-cv-00061-JPB, ECF No. 20, ¶ 7.

87. Upon information and belief, Mylan Inc., directly or through MPI is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in Pennsylvania and throughout the United States.

88. This Court has general personal jurisdiction over Mylan Inc. because, *inter alia*, Mylan Inc. is an entity organized under the laws of Pennsylvania; maintains its principal place of business in Canonsburg, Pennsylvania; Mylan Inc. has availed itself of the rights and benefits of Pennsylvania law; and has engaged in substantial and continuing contacts with Pennsylvania.

89. In addition, upon information and belief, Mylan Inc. alone and/or together with its affiliate and/or agent MPI has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement under 35 U.S.C. § 271 that has led and/or will lead to foreseeable harm and injury to Momenta in Pennsylvania.

90. Upon information and belief, Mylan, Inc. is a wholly owned subsidiary of Viatris, which exercises considerable control over Mylan, Inc. (Ex. 11 – Viatris Inc. Form 10-K, 2022 at 165).

91. This Court has general personal jurisdiction over Viatris because, *inter alia,* Viatris maintains its principal place of business in Canonsburg, Pennsylvania, has availed itself of the rights and benefits of Pennsylvania law, and has engaged in substantial and continuing contacts with Pennsylvania. In addition, Viatris, alone and/or together with its affiliates Mylan Inc. and MPI, has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement under 35 U.S.C. § 271 that has led and/or will lead to foreseeable harm and injury to Momenta in Pennsylvania.

92. Upon information and belief, MPI, Mylan Inc., and Viatris hold themselves out as a unitary entity and represent to the public that their activities are directed, controlled, and carried out as a single entity for purposes of manufacturing, selling, marketing, distribution and importation of generic drug products in Pennsylvania and throughout the United States.

93. Upon information and belief, MPI, Mylan Inc., and Viatris Inc. are agents of each other with respect to formulating, manufacturing, packaging, importing, marketing and/or selling pharmaceutical products throughout the United States and with respect to Mylan's Glatiramer Acetate Products.

94. Upon information and belief, MPI, Mylan Inc., and Viatris Inc. are acting in concert with each other with respect to formulating, manufacturing, packaging, importing, marketing and/or selling pharmaceutical products throughout the United States and with respect to Mylan's Glatiramer Acetate Products.

Defendant Mylan Teoranta

95. This Court has specific personal jurisdiction over Mylan Teoranta pursuant to due process and/or the Pennsylvania Long Arm Statute by virtue of the fact that, *inter alia*, Mylan Teoranta has committed or induced tortious acts of patent infringement under 35 U.S.C. § 271 in Pennsylvania and intends a future course of conduct that includes committing or inducing acts of patent infringement in Pennsylvania. Alternatively, personal jurisdiction also exists over foreign defendant Mylan Teoranta because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met.

96. Upon information and belief, Mylan Teoranta partners with Viatris, Mylan Inc., and MPI to manufacture and market generic glatiramer acetate products in the United States, including in this District. (*See, e.g.*, Ex. 38 – Mylan 40mg/mL label 16; Ex. 10 – Irish Times Article).

97. Upon information and belief, Mylan Teoranta has engaged in and maintained systematic and continuous business contacts within the Commonwealth of Pennsylvania and has purposefully availed itself of the benefits and protections of the laws of Pennsylvania.

98. Upon information and belief, Mylan Teoranta has filed ANDAs with the FDA and has marketed generic pharmaceutical products in the Commonwealth of Pennsylvania, including, *inter alia*, levoleucovorin calcium.

99. Upon information and belief, Mylan Teoranta has agreements with pharmaceutical retailers, wholesalers or distributors providing for the distribution of its products in the Commonwealth of Pennsylvania, including, *inter alia*, levoleucovorin calcium.

100. Upon information and belief, Mylan Teoranta formulates Mylan Glatiramer Acetate Products for distribution and sale throughout the United States, including this judicial

District, and alone and/or together with its affiliates and/or agents Mylan Teoranta imports, markets, sells, and/or offers for sale said products in the Commonwealth of Pennsylvania.

101. Upon information and belief, this Court has personal jurisdiction over Mylan Teoranta for the reasons stated herein, including, *inter alia*, Mylan Teoranta's activities in the forum, activities directed at the forum, and significant contacts with the forum, all of which render Mylan Teoranta at home in the forum.

102. Alternatively, this Court may exercise personal jurisdiction over Mylan Teoranta under Federal Rule of Civil Procedure 4(k)(2) because: (a) Plaintiff's claims arise under federal law; (b) Mylan Teoranta is a foreign defendant not subject to personal jurisdiction in any state's courts of general jurisdiction; and (c) Mylan Teoranta has sufficient contacts with the United States as a whole, including but not limited to manufacturing and/or selling pharmaceutical products like the Mylan Glatiramer Acetate Products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Mylan Teoranta satisfies due process.

Defendant Natco

103. This Court has specific personal jurisdiction over Natco pursuant to due process and/or the Pennsylvania Long Arm Statute by virtue of the fact that, *inter alia*, Natco has committed or induced tortious acts of patent infringement under 35 U.S.C. § 271 in Pennsylvania, and intends a future course of conduct that includes committing or inducing acts of patent infringement in Pennsylvania. Alternatively, personal jurisdiction also exists over foreign defendant Natco because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met.

104. Upon information and belief, Natco partners with Mylan to manufacture and market generic glatiramer acetate products in the United States, including in this District. (*See* Ex. 27 – 2008.06.10 Mylan Press Release; Ex. 29 – Hindu Article; Ex. 40 – Natco Contract Manufacturing

Page; *see also* Ex. 41 – Natco International Formulations Page; Ex. 42 – Natco 2019–20 Annual Report, at 12).

105. Upon information and belief, Natco has engaged in and maintained systematic and continuous business contacts within the Commonwealth of Pennsylvania, and has purposefully availed itself of the benefits and protections of the laws of Pennsylvania.

106. Upon information and belief, Natco Pharma, Inc. is a wholly-owned subsidiary of Natco Pharma Ltd. (Ex. 43 – Natco 2020-21 Annual Report, at 174). Upon information and belief, Natco Pharma, Inc. is a business located at 241 West Roseville Road, Lancaster, PA 17601. (Ex. 44 – Pennsylvania Department of State Business Entity Report for Natco Pharma, Inc.). Natco has purposefully availed itself of the benefits and protections of the laws of Pennsylvania by maintaining a place of business in Pennsylvania.

107. Upon information and belief, Natco routinely files Abbreviated New Drug Applications ("ANDAs") with the United States Food and Drug Administration ("FDA") and markets dozens of generic pharmaceutical products in the Commonwealth of Pennsylvania, including, *inter alia*, alprazolam, armodafinil, lansoprazole, ondansetron hydrochloride, rizatriptan benzoate, and trihexyphenidyl hydrochloride.

108. Upon information and belief, Natco has agreements with pharmaceutical retailers, wholesalers or distributors providing for the distribution of its products in the Commonwealth of Pennsylvania, including, *inter alia*, alprazolam, armodafinil, lansoprazole, ondansetron hydrochloride, rizatriptan benzoate, and trihexyphenidyl hydrochloride.

109. Upon information and belief, Natco (including through its business partner Mylan) imports, markets, sells, and/or offers for sale Mylan Glatiramer Acetate Products and/or glatiramer acetate for use in Mylan Glatiramer Acetate Products in the Commonwealth of Pennsylvania. (*See*

Ex. 36 – 2018.12.06 Bill of Lading; Ex. 60 – 2018.05.09 Bill of Lading; Ex. 61 – 2018.01.02 Bill of Lading; Ex. 59 – Customs Ruling; *see also* Ex. 27 – 2008.06.10 Mylan Press Release; Ex. 29 – Hindu Article; Ex. 40 – Natco Contract Manufacturing Page; Ex. 41 – Natco International Formulations Page; Ex. 42 – Natco 2019–20 Annual Report, at 12).

110. Upon information and belief, this Court has personal jurisdiction over Natco for the reasons stated herein, including, *inter alia*, Natco's activities in the forum, activities directed at the forum, and significant contacts with the forum, all of which render Natco at home in the forum.

111. Alternatively, this Court may exercise personal jurisdiction over Natco under Federal Rule of Civil Procedure 4(k)(2) because: (a) Plaintiff's claims arise under federal law; (b) Natco is a foreign defendant not subject to personal jurisdiction in any state's courts of general jurisdiction; and (c) Natco has sufficient contacts with the United States as a whole, including but not limited to manufacturing and/or selling pharmaceutical products like the Mylan Glatiramer Acetate Products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Natco satisfies due process.

Defendant Gland

112. This Court has specific personal jurisdiction over Gland pursuant to due process and/or the Pennsylvania Long Arm Statute by virtue of the fact that, *inter alia*, Gland has committed or induced tortious acts of patent infringement under 35 U.S.C. § 271 in Pennsylvania and intends a future course of conduct that includes committing or inducing acts of patent infringement in Pennsylvania. Alternatively, personal jurisdiction also exists over foreign defendant Gland because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met.

113. Upon information and belief, Gland partners with Mylan to manufacture, import and/or market generic glatiramer acetate products in the United States, including in this District.

(*See, e.g.*, Ex. 39 – Mylan 20mg/ml label, at 15; Ex. 45 – Money Control News Article Regarding Natco).

114. Upon information and belief, Gland has engaged in and maintained systematic and continuous business contacts within Commonwealth of Pennsylvania and has purposefully availed itself of the benefits and protections of the laws of Pennsylvania.

115. Upon information and belief, Gland has shipped large quantities of pharmaceutical products from India to Philadelphia Regional Port Authority, Philadelphia, Pennsylvania. Gland has purposefully availed itself of the benefits and protections of the laws of Pennsylvania by importing its products into Pennsylvania.

116. Upon information and belief, Gland files ANDAs and markets generic pharmaceutical products in the Commonwealth of Pennsylvania, including, *inter alia*, magnesium sulfate.

117. Upon information and belief, Gland has agreements with pharmaceutical retailers, wholesalers or distributors providing for the distribution of its products in the Commonwealth of Pennsylvania, including, *inter alia*, magnesium sulfate.

118. Upon information and belief, Gland formulates and/or manufactures Mylan Glatiramer Acetate Products for distribution and sale throughout the United States, including in the Commonwealth of Pennsylvania, and either alone and/or through its business partner Mylan imports, markets, sells, and offers for sale said products in the Commonwealth of Pennsylvania.

119. Upon information and belief, this Court has personal jurisdiction over Gland for the reasons stated herein, including, *inter alia*, Gland's activities in the forum, activities directed at the forum, and significant contacts with the forum, all of which render jurisdiction in this Court proper.

120. Alternatively, this Court may exercise personal jurisdiction over Gland under Federal Rule of Civil Procedure 4(k)(2) because: (a) Plaintiff's claims arise under federal law; (b) Gland is a foreign defendant not subject to personal jurisdiction in any state's courts of general jurisdiction; and (c) Gland has sufficient contacts with the United States as a whole, including but not limited to manufacturing and/or selling pharmaceutical products like the Mylan Glatiramer Acetate Products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Gland satisfies due process.

C. Venue

121. Venue is proper in this district pursuant to the provisions of 28 U.S.C. §§ 1391(b)(c), (d) and 1400(b).

122. Venue is proper in this district for Viatris, Mylan Inc., and MPI pursuant to the provisions of 28 U.S.C. §§ 1391(b), (c), (d) and 1400(b) because they reside in this District and/or have a permanent and continuous presence in, have committed acts of infringement in, and maintain regular and established places of businesses in this District.

123. By registering to conduct business in Pennsylvania and by having facilities where they regularly conduct business in this District, Viatris, Mylan Inc., and MPI have a permanent and continuous presence and regular and established places of business in the Western District of Pennsylvania.

124. Viatris maintains a principal place of business in this District and therefore has a regular and established place of business in the Western District of Pennsylvania for purposes of venue under 28 U.S.C. §1400(b). (*See, e.g.*, Ex. 11 – Viatris Form 10-K).

125. Viatris has committed acts of direct infringement in this judicial District itself and/or through its wholly owned subsidiaries Mylan Inc. and MPI. For example, upon information

and belief, Viatris, itself and/or through its wholly owned subsidiaries Mylan Inc. and MPI, which act as agents and alter egos of Viatris and are completely controlled and dominated by Viatris, performs acts of infringement in this District by manufacturing, importing, marketing, selling and/or distributing Mylan Glatiramer Acetate Products in this District, including at 1000 Mylan Blvd., Canonsburg, PA 15317. Upon information and belief, Viatris also performs acts in this District constituting inducement of MPI, Mylan Inc., Mylan Teoranta, Natco, and/or Gland to perform acts of infringement by manufacturing, importing, marketing, selling and/or distributing Mylan Glatiramer Acetate Products in this District and elsewhere in the United States.

126. Mylan Inc. is an entity organized under the laws of Pennsylvania and maintains a principal place of business in this District. (*See* Ex. 6 – Mylan Form S-4). Mylan Inc. therefore resides in the Western District of Pennsylvania for purposes of venue under 28 U.S.C. §1400(b). Mylan has previously conceded that venue is proper in this District for Mylan Inc. as a Pennsylvania corporation. *See Bausch Healthcare Ireland Ltd. et al. v. Mylan Labs Ltd. et al.*, No. 2:21-cv-573-WSH, ECF No. 62-4 at 8 n.5 (W.D. Pa.).

127. Mylan Inc. has committed acts of direct infringement in this judicial District itself and/or through its wholly owned subsidiary MPI. For example, upon information and belief, Mylan Inc., itself and/or through its wholly owned subsidiary MPI, which acts as an agent and alter ego of Mylan Inc. and is completely controlled and dominated by Mylan Inc., performs acts of infringement in this District by manufacturing, importing, marketing, selling and/or distributing Mylan Glatiramer Acetate Products in this District, including at 1000 Mylan Blvd., Canonsburg, PA 15317. Upon information and belief, Mylan Inc. also performs acts in this District constituting inducement of Viatris, MPI, Mylan Teoranta, Natco, and/or Gland to perform acts of infringement

by manufacturing, importing, marketing, selling and/or distributing Mylan Glatiramer Acetate Products in this District and elsewhere in the United States.

128. Upon information and belief, MPI maintains a regular and established place of business, including office space for its employees and officers, in this District, at 1000 Mylan Blvd., Canonsburg, PA 15317. Mylan has previously conceded that MPI maintains a regular and established place of business in this judicial District. *See Bausch Healthcare Ireland Ltd. et al. v. Mylan Labs Ltd. et al.*, No. 2:21-cv-573-WSH, ECF No. 62-4 at 13 n.7 (W.D. Pa.).

129. MPI has numerous employees and officers in this judicial District, based at 1000 Mylan Blvd., Canonsburg, PA 15317. Upon information and belief, several of MPI's current officers, including its Secretary, Treasurer, and Director, are based at MPI's Canonsburg, PA location. (Ex. 46 – W.Va. Secretary of State Business Entity Details for MPI). Upon information and belief, MPI also has employment opportunities for its Western District of Pennsylvania location. (*See* Ex. 47 – MPI Digital Marketing Job Posting; Ex. 64 – MPI Marketing Manager Job Posting). Upon information and belief, the jobs for which MPI has openings would include responsibilities relating to the sale of Mylan Glatiramer Acetate Products, including within this judicial District. (*See id.*).

130. MPI has committed acts of infringement in this judicial District. For example, upon information and belief, MPI is responsible for at least the manufacture, sale, and/or importation of the Mylan Glatiramer Acetate Products. (*See, e.g.,* Ex. 38 – Mylan 40mg/mL Label, at 16; Ex. 39 – Mylan 20mg/mL Label, at 15; Ex. 33 – Viatris Glatiramer Acetate Website (noting that the trademark for the Mylan Glatiramer Acetate Products is registered to MPI)). MPI infringes the patents-in-suit in this District by manufacturing, importing, marketing, selling and/or distributing Mylan Glatiramer Acetate Products in this District, including at 1000 Mylan Blvd., Canonsburg,

PA 15317. Upon information and belief, MPI also performs acts in this District constituting inducement of Viatris, Mylan Inc., Mylan Teoranta, Natco, and/or Gland to perform acts of infringement by manufacturing, importing, marketing, selling and/or distributing Mylan Glatiramer Acetate Products in this District and elsewhere in the United States.

131. Venue is also proper because MPI is a wholly-owned subsidiary of Mylan Inc. and Viatris, operates as an agent and alter-ego of Mylan Inc. and Viatris, and is completely controlled and dominated by Mylan Inc. and Viatris. Viatris and Mylan Inc. direct and are involved in the activities of MPI, and they operate as a single company. As the corporate parents of MPI, Viatris and MPI have participated in the commission of patent infringement in this judicial District, including by manufacturing, importing, marketing, selling and/or distributing Mylan Glatiramer Acetate Products in this District and elsewhere in the United States that led to foreseeable harm and injury to Momenta in Pennsylvania. Upon information and belief, the officers of MPI are also officers of Viatris and Mylan Inc. For example, John Miraglia, the current Director and Treasurer of MPI, was a signatory to a June 16, 2020 amendment to a Revolving Credit Agreement on behalf of both Mylan Inc and Mylan N.V. (now Viatris). (*See* Ex. 48 at 3.) Thomas Salus, the current Secretary of MPI, also serves as Viatris's Deputy Global General Counsel and Assistant Secretary, according to Mr. Salus's apparent LinkedIn profile page. (*See* Ex. 46 – W.Va. Secretary of State Business Entity Details for MPI; Ex. 49 – Salus LinkedIn Profile Page).

132. Venue is proper in this district for Mylan Teoranta pursuant to the provisions of 28 U.S.C. §§ 1391(b), (c), (d) and 1400(b) because Mylan Teoranta is a company organized and existing under the laws of Ireland and may be sued in any judicial district.

133. Venue is proper in this district for Natco pursuant to the provisions of 28 U.S.C. §§ 1391(b), (c), (d) and 1400(b) because Natco is a company organized and existing under the laws of India and may be sued in any judicial district.

134. Venue is proper in this district for Gland pursuant to the provisions of 28 U.S.C. §§ 1391(b), (c), (d) and 1400(b) because Gland is a company organized and existing under the laws of India and may be sued in any judicial district.

COUNT I
(Infringement Of U.S. Patent No. 8,859,489 By Defendants Under, *Inter Alia*, 35 U.S.C. § 271(b) and/or (g))

135. Paragraphs 1 through 134 are incorporated by reference as if fully stated herein.

136. The '489 patent is valid and enforceable.

137. Upon information and belief, Mylan Teoranta, Natco Pharma Ltd., and Gland Pharma, Ltd. currently infringe and have infringed one or more claims of the '489 patent, including at least claim 1, either literally or under the doctrine of equivalents, by, *inter alia*, manufacturing generic glatiramer acetate for commercial sale using the methods claimed in the '489 patent and, without authority, importing that generic glatiramer acetate (either alone or as the active ingredient of the Mylan Glatiramer Acetate Products) into the United States or making, offering to sell, selling, or using it within the United States, or inducing others to do the same.

138. Upon information and belief, Mylan Pharmaceuticals, Inc., Mylan Inc., and Viatris Inc. have infringed, and are continuing to infringe, and have induced others to infringe, the '489 patent, either literally or under the doctrine of equivalents, by, *inter alia,* importing, without authority, generic glatiramer acetate (either alone or as the active ingredient of the Mylan Glatiramer Acetate Products) into the United States or making, offering to sell, selling, or using it within the United States, or inducing others to do the same.

139. For example, upon information and belief, Defendants have induced infringement, and continue to induce infringement, of one or more claims of the '489 patent under 35 U.S.C. § 271(b). Defendants actively, knowingly, and intentionally induced, and continue to actively, knowingly, and intentionally induce, infringement of the '489 patent by importing, selling or otherwise supplying generic glatiramer acetate (either alone or as the active ingredient of the Mylan Glatiramer Acetate Products); with the knowledge and intent that other Defendants or third parties will use, sell, and/or offer for sale in the United States, and/or import into the United States, the generic glatiramer acetate to infringe the '489 patent; and with the knowledge and intent to encourage and facilitate the infringement through the importation or dissemination of the generic glatiramer acetate and/or the creation and dissemination of promotional and marketing materials, supporting materials, instructions, product manuals, and/or technical information related to the generic glatiramer acetate.

140. Defendants have not obtained a license to use the processes claimed in the '489 patent or to import, make, offer for sale, sell, or use in the United States products made by those processes.

141. Upon information and belief, Defendants have acted in concert by assisting with, participating in, encouraging, contributing, aiding and abetting and/or directing the manufacture, marketing, sale, offer to sell and/or import of the Mylan Glatiramer Acetate Products.

142. The accused products are glatiramer acetate and products containing the same, manufactured using a process claimed by the '489 patent, literally and/or under the doctrine of equivalents. Upon information and belief, glatiramer acetate is being manufactured using a process claimed by the '489 Patent outside of the United States by Natco, Mylan Teoranta, and/or Gland, working in conjunction with Mylan, which is then imported into the United States by Defendants,

and then sold by Defendants, specifically including at least MPI, Viatris, and Mylan Inc. On October 3, 2017, after MPI had obtained approval to market the Mylan Glatiramer Acetate Products in the United States, Mylan N.V. (now Viatris) stated that it would begin shipping its glatiramer acetate products "imminently," and on October 4, 2017, Mylan N.V. (now Viatris) confirmed that it had launched Glatiramer Acetate Injection 40 mg/mL and 20 mg/mL in the United States. (Ex. 20 – 091646 Approval Letter; Ex. 21 – 206936 Approval Letter; Ex. 25 – 2017.10.03 Mylan Press Release; Ex. 26 – 2017.10.04 Mylan Press Release).

143. Upon information and belief, Defendants make, offer to sell, sell and/or import glatiramer acetate that is manufactured using a process claimed by the asserted claims of the '489 patent literally and/or under the doctrine of equivalents.

144. Claim 1 of the '489 patent recites as follows:

> *A method for preparing a composition comprising purified glatiramer acetate having a pyro-Glu concentration of 2000–7000 ppm and a Mp of 5000–9000 Da, comprising: polymerizing N-carboxy anhydrides of L-alanine, benzyl-protected L-glutamic acid, trifluoroacetic acid (TFA) protected L-lysine and L-tyrosine to generate a protected copolymer (Intermediate-1); treating the protected copolymer with HBr and acetic acid to partially depolymerize the protected copolymer and deprotect benzyl protected groups thereby generating a partially depolymerized product; treating the partially depolymerized product with piperidine to deprotect TFA-protected lysines thereby generating glatiramer acetate; and purifying the glatiramer acetate to create purified glatiramer acetate having a pyro-Glu concentration of 2000-7000 ppm and a Mp of 5000–9000 Da, wherein water is present during the entirety of the depolymerization step in an amount that yields glatiramer acetate having a pyro-Glu concentration of 2000–7000 ppm and a Mp of 5000–9000 Da.*

145. Upon information and belief, Defendants' manufacturing process for the Mylan Glatiramer Acetate Products comprises "[a] method for preparing a composition comprising purified glatiramer acetate having a pyro-Glu concentration of 2000–7000 ppm." According to

Mylan, its ANDA included "rigorous side-by-side analyses, including characterization data, [demonstrating] that Mylan's Glatiramer Acetate Injection 20 mg/mL and 40 mg/mL have the same active ingredient" as Copaxone® (glatiramer acetate injection). (Ex. 25 – 2017.10.03 Press Release). And given the FDA's approval of Mylan's Glatiramer Acetate Products, the FDA also considers those products to have established "sameness" to Copaxone® (glatiramer acetate injection). As the FDA has recognized, pyro-Glu[8] is a process signature for glatiramer acetate synthesis because endo glutamic acid cyclizes to form pyro-Glu under strong acid conditions resulting in cleavage such that pyro-Glu becomes the "new" N terminus. (*See* Ex. 16 – FDA CP Response, at 18 n.61, 28). The claimed pyro-Glu range is representative of the distribution of pyro-Glu across multiple lots of Copaxone® (glatiramer acetate injection). (*See, e.g.*, Ex. 1 – '489 patent at 4:14–20). Because Mylan has represented, and the FDA has found, that the Mylan Glatiramer Acetate Products are the "same" as Copaxone® (glatiramer acetate injection), upon information and belief, those products share the same pyro-Glu concentration as Copaxone® (glatiramer acetate injection), *i.e.*, the claimed range. Upon information and belief, the Mylan Glatiramer Acetate Products are made from purified glatiramer acetate having a pyro-Glu concentration of 2000–7000 ppm.

146. Upon information and belief, Defendants' manufacturing process for the Mylan Glatiramer Acetate Products also results in glatiramer acetate having "a Mp of 5000–9000 Da." "Mp", or "peak molecular weight" (*see* Ex. 1 – '489 Patent, at 4:42–45), is the molecular weight corresponding to the peak of the distribution curve of molecular weights in a composition. Like pyro-Glu concentration, "[m]olecular [w]eight [d]istribution" is one of the physicochemical

[8] The FDA CP response refers to pyro-glutamate in particular. Nevertheless, as discussed above, *supra*, p. 5 n.3, a person of skill in the art would understand that pyro-Glu and pyro-glutamate are interchangeable in the context of the '374 and '489 Patents.

properties of glatiramer acetate which must match that of Copaxone® (glatiramer acetate injection). (*See* Ex. 16 – FDA CP Response, at 23). And the glatiramer acetate in Copaxone® (glatiramer acetate injection) has a peak average molecular weight of 5000–9000 Da. (*See id.* at 24; Ex. 15 – Copaxone Package Insert, at 3). Accordingly, the approved label for Mylan's 20 mg/mL and 40 mg/mL Glatiramer Acetate Products states that the average molecular weight of the glatiramer acetate is "5,000 to 9,000 daltons." (*See* Ex. 38 – Mylan 40mg Label, at 6; Ex. 39 – Mylan 20mg Label, at 6).

147. Upon information and belief, Defendants' manufacturing process for the Mylan Glatiramer Acetate Products comprises "polymerizing N-carboxy anhydrides of L-alanine, benzyl-protected L-glutamic acid, trifluoroacetic acid (TFA) protected L-lysine and L-tyrosine to generate a protected copolymer (Intermediate-1)." Defendants manufacture glatiramer acetate using this step of the claimed method because this step of the claimed method follows the fundamental synthetic scheme for glatiramer acetate identified by the FDA. (*See* Ex. 16 – FDA CP Response, at 13 & nn.44–46). Equivalence of the fundamental synthetic scheme is a requirement for FDA approval of generic versions of Copaxone® (glatiramer acetate injection). (Ex. 19 – FDA Draft Guidance, at 1–2). Mylan has represented that it meets the criteria set forth in the FDA CP Response. (*See* Ex. 50 – 2015.05.29 Mylan Conference Transcript, at 5; Ex. 51 – 2015.06.09 Mylan Conference Transcript, at 13). In the first step of Defendants' synthetic process for glatiramer acetate, "N-carboxyanhydrides of the amino acids alanine, glutamic acid, lysine, and tyrosine are combined with the initiator diethylamine to form long chains." (Ex. 58 – Order, *Teva Pharms. USA, Inc. et al. v. Sandoz, Inc., et al*., No. 1:08-cv-07611 (S.D.N.Y. June 29, 2012), ECF No. 336 at 79). Defendants use benzyl-protected glutamic acid and TFA-protected lysine as starting materials for Step 1. *Id*. Defendants' Step 1 results in a copolymer retaining benzyl

protecting groups on the glutamic acid residues and TFA protecting groups on the lysine residues, *i.e.*, a protected copolymer (Intermediate-1). (*Id.* at 79–80).

148. Upon information and belief, Defendants' manufacturing process for the Mylan Glatiramer Acetate Products comprises "treating the protected copolymer with HBr and acetic acid to partially depolymerize the protected copolymer and deprotect benzyl protected groups thereby generating a partially depolymerized product." This step is also part of the fundamental glatiramer acetate synthetic scheme, (*see* Ex. 16 – FDA CP Response, at 13–14 & nn.44–46; Ex. 19 – FDA Draft Guidance, at 2), which Mylan has represented that it follows, (*see* Ex. 50 – 2015.05.29 Mylan Conference Transcript, at 5; Ex. 51 – 2015.06.09 Mylan Conference Transcript, at 13). In the second step of Defendants' synthetic process for glatiramer acetate, the protected copolymer is treated with HBr/acetic acid, removing the benzyl protecting groups and cleaving the polypeptide chains. (Ex. 58 – Order, *Teva Pharms. USA, Inc. et al. v. Sandoz, Inc., et al*., No. 1:08-cv-07611 (S.D.N.Y. June 29, 2012), ECF No. 336 at 80 ("[T]he addition of HBR/acetic acid serves two purposes. First, it removes the benzyl protecting groups from the glutamic acids. Second, it cleaves, or cuts, the polypeptide chains.")). The result of this step is a partially depolymerized copolymer retaining TFA protecting groups. *Id*.

149. Upon information and belief, Defendants' manufacturing process for the Mylan Glatiramer Acetate Products comprises "treating the partially depolymerized product with piperidine to deprotect TFA-protected lysines thereby generating glatiramer acetate." This step is also part of the fundamental glatiramer acetate synthetic scheme required by the FDA, (*see* Ex. 16 – FDA CP Response, at 13–14 & nn.44–46; Ex. 19 – FDA Draft Guidance, at 2), which Mylan has represented that it follows (*see* Ex. 50 – 2015.05.29 Mylan Conference Transcript, at 5; Ex. 51 – 2015.06.09 Mylan Conference Transcript, at 13). In the third step of Defendants' synthetic

process for glatiramer acetate, the partially depolymerized copolymer is treated with piperidine to remove the TFA protecting groups from lysine residues. (Ex. 58 – Order, *Teva Pharms. USA, Inc. et al. v. Sandoz. Inc., et al*., No. 1:08-cv-07611 (S.D.N.Y. June 29, 2012), ECF No. 336 at 83–84 ("In Step 3 of Mylan's process, TFA-copolymer-1 is treated with piperidine, which removes the TFA protecting groups from the lysines.")). The result of this step is crude glatiramer acetate. (*See id*; Ex. 16 – FDA CP Response, at 13–14 and nn.44–46).

150. Upon information and belief, Defendants' manufacturing process for the Mylan Glatiramer Acetate Products comprises "purifying the glatiramer acetate to create purified glatiramer acetate having a pyro-Glu concentration of 2000–7000 ppm and a Mp of 5000–9000 Da." The fourth step of Defendants' synthetic process for glatiramer acetate is purification by diafiltration using acetic acid. (Ex. 58 – Order, *Teva Pharms. USA, Inc. et al. v. Sandoz. Inc., et al*., No.1:08-cv-07611 (S.D.N.Y. June 29, 2012), ECF No. 336 at 84 ("In Step 4 of Mylan's process . . . the resulting product from Step 3 is purified by diafiltration using acetic acid.")). Upon information and belief, purification is a step that Defendants perform as part of commercial manufacture. As discussed above, Mylan's Glatiramer Acetate Products are prepared from glatiramer acetate considered by the FDA to have established "sameness" to Copaxone® (glatiramer acetate injection), including having pyro-Glu concentration and Mp within the recited ranges.

151. Upon information and belief, in Defendants' manufacturing process for the Mylan Glatiramer Acetate Products, "water is present during the entirety of the depolymerization step in an amount that yields glatiramer acetate having a pyro-Glu concentration of 2000–7000 ppm and a Mp of 5000–9000 Da." The FDA guidance for approval of generic glatiramer acetate notes that water has a role in the cleavage reactions during the partial depolymerization step. (Ex. 16 – FDA

CP Response, at 25–26 n.87; Ex. 19 – FDA Draft Guidance, at 1 n.1). The FDA has further advised ANDA applicants like Mylan that "equivalence of [] structural signatures" like those resulting from the cleavage during partial depolymerization is necessary to ensure that a proposed generic glatiramer acetate will be the same as Copaxone® (glatiramer acetate injection). (Ex. 16 – FDA CP Response, at 26). Given the FDA's publication of the role of water in that depolymerization step, and the FDA's simultaneous advisement that the parameters of that depolymerization step must be controlled to ensure sameness with Copaxone® (glatiramer acetate injection), upon information and belief, Defendants control the presence of water during the depolymerization step to control the commercial manufacturing process of generic glatiramer acetate, due to the relationship between water, pyro-Glu concentration, and peak molecular weight. (*See* Ex. 1 – '489 Patent, at 4:21–45 (discussing relationship between water, pyro-Glu concentration, and peak molecular weight)). Specifically, upon information and belief, Defendants ensure that water is present during the entirety of the depolymerization step in an amount that yields glatiramer acetate having a pyro-Glu concentration and Mp within the claimed ranges.

152. Alternatively, to the extent the Mylan Glatiramer Acetate Products are not manufactured by a process that literally falls within the claims of the '489 patent, upon information and belief, the Mylan Glatiramer Acetate Products are manufactured by a method that performs substantially the same function in substantially the same way with substantially the same result as the methods claimed in the '489 patent. In addition, Defendants' Mylan Glatiramer Acetate Products are manufactured using a method that is insubstantially different from the methods claimed in the '489 patent. For example, like the methods claimed in the '489 patent, Defendants' manufacturing process for their Mylan Glatiramer Acetate Products ensures that those products are the same as the active ingredient in Copaxone®. (*See* Ex. 25 – 2017.10.03 Mylan Press Release,

at 1–2; Ex. 50 – 2015.05.29 Mylan Conference Transcript, at 5; Ex. 51 – 2015.06.09 Mylan Conference Transcript, at 13).

153. Upon information and belief, Mylan has had knowledge and notice of the '489 patent and is knowingly and willfully infringing the '489 patent.

154. Mylan's conduct in infringing the '489 patent renders this case exceptional within the meaning of 35 U.S.C. § 285.

COUNT II
(Infringement Of U.S. Patent No. 9,395,374 By Defendants Under, *Inter Alia*, 35 U.S.C. § 271(b) and/or (g))

155. Paragraphs 1 through 154 are incorporated by reference as if fully stated herein.

156. The '374 patent is valid and enforceable.

157. Upon information and belief, Mylan Teoranta, Natco Pharma Ltd., and Gland Pharma, Ltd. currently infringe and have infringed one or more claims of the '374 patent, including at least claim 1, either literally or under the doctrine of equivalents, by, *inter alia*, manufacturing generic glatiramer acetate for commercial sale using the methods claimed in the '374 patent and, without authority, importing that generic glatiramer acetate (either alone or as the active ingredient of the Mylan Glatiramer Acetate Products) into the United States or making, offering to sell, selling, or using it within the United States, or inducing others to do the same.

158. Upon information and belief, Mylan Pharmaceuticals, Inc., Mylan Inc., and Viatris Inc. have infringed, and are continuing to infringe, and have induced others to infringe, the '374 patent, either literally or under the doctrine of equivalents, by, *inter alia,* importing, without authority, generic glatiramer acetate (either alone or as the active ingredient of the Mylan Glatiramer Acetate Products) into the United States or making, offering to sell, selling, or using it within the United States, or inducing others to do the same.

159. For example, upon information and belief, Defendants have induced infringement, and continue to induce infringement, of one or more claims of the '374 patent under 35 U.S.C. § 271(b). Defendants actively, knowingly, and intentionally induced, and continue to actively, knowingly, and intentionally induce, infringement of the '374 patent by importing, selling, or otherwise supplying generic glatiramer acetate (either alone or as the active ingredient of the Mylan Glatiramer Acetate Products); with the knowledge and intent that other Defendants or third parties will use, sell, and/or offer for sale in the United States, and/or import into the United States, the generic glatiramer acetate to infringe the '374 patent; and with the knowledge and intent to encourage and facilitate the infringement through the importation or dissemination of the generic glatiramer acetate and/or the creation and dissemination of promotional and marketing materials, supporting materials, instructions, product manuals, and/or technical information related to the generic glatiramer acetate.

160. Defendants have not obtained a license to use the processes claimed in the '374 patent or to import, use, make, offer for sale, or sell in the United States products made by those processes.

161. Upon information and belief, Defendants have acted in concert by assisting with, participating in, encouraging, contributing, aiding and abetting and/or directing the manufacture, marketing, sale, offer to sell and/or import of the Mylan Glatiramer Acetate Products.

162. The accused products are glatiramer acetate and products containing the same, manufactured using a process claimed by the '374 patent, literally and/or under the doctrine of equivalents. Upon information and belief, glatiramer acetate is being manufactured using a process claimed by the '374 patent outside of the United States by Natco, Mylan Teoranta, and/or Gland, working in conjunction with Mylan, which is then imported into the United States by Defendants,

and then sold by Defendants, specifically including at least MPI, Viatris, and Mylan Inc. On October 3, 2017, after MPI had obtained approval to market the Mylan Glatiramer Acetate Products in the United States, Mylan N.V. (now Viatris) stated that it would begin shipping its glatiramer acetate products "imminently," and on October 4, 2017, Mylan N.V. (now Viatris) confirmed that it had launched Glatiramer Acetate Injection 40 mg/mL and 20 mg/mL in the United States. (Ex. 20 – 091646 Approval Letter; Ex. 21 – 206936 Approval Letter; Ex. 25 – 2017.10.03 Mylan Press Release; Ex. 26 – 2017.10.04 Mylan Press Release).

163. Upon information and belief, Defendants make, offer to sell, sell and/or import glatiramer acetate using a process claimed by the asserted claims of the '374 patent literally and/or under the doctrine of equivalents.

164. Claim 1 of the '374 patent recites as follows:

> *A method for manufacturing a pharmaceutical composition comprising glatiramer acetate, the method comprising:*
>
> *preparing an amino acid copolymer of L-glutamic acid, L-alanine, L-lysine, and L-tyrosine, wherein the preparing step comprises co-polymerizing N-carboxy anhydrides of L-alanine, benzyl-protected L-glutamic acid, trifluoroacetic acid (TFA)-protected L-lysine, and L-tyrosine to generate a first material; treating the first material to deprotect the benzyl-protected L-glutamic acid therein and to partially depolymerize the first material, thereby generating a second material; treating the second material to deprotect the TFA-protected L-lysine to produce a third material; and purifying the third material, to thereby produce the copolymer of L-glutamic acid, L-alanine, L-lysine, and L-tyrosine;*
>
> *measuring pyro-glutamate content of the copolymer in a sample of the copolymer;*
>
> *measuring the peak average molecular weight (Mp) of the copolymer;*
>
> *processing the copolymer to produce a pharmaceutical composition comprising glatiramer acetate only if the measured pyro-glutamate*

content of the copolymer in the sample is within 2000–7000 parts per million (ppm) on a dry weight/dry weight basis,

thereby producing a pharmaceutical composition comprising glatiramer acetate.

165. Defendants' manufacturing process for the Mylan Glatiramer Acetate Products comprises "[a] method for manufacturing a pharmaceutical composition comprising glatiramer acetate." As discussed above, the active pharmaceutical ingredient of the Mylan Glatiramer Acetate Products is glatiramer acetate.

166. Upon information and belief, Defendants' manufacturing process for the Mylan Glatiramer Acetate Products comprises "preparing an amino acid copolymer of L-glutamic acid, L-alanine, L-lysine, and L-tyrosine, wherein the preparing step comprises co-polymerizing N-carboxy anhydrides of L-alanine, benzyl-protected L-glutamic acid, trifluoroacetic acid (TFA)-protected L-lysine, and L-tyrosine to generate a first material." Defendants manufacture glatiramer acetate by this step of the claimed method because this step of the method follows the fundamental synthetic scheme for glatiramer acetate identified by the FDA. (*See* Ex. 16 – FDA CP Response, at 13 and nn.44–46). Equivalence of fundamental synthetic scheme is a requirement for FDA approval of generic versions of Copaxone® (glatiramer acetate injection). (Ex. 19 – FDA Draft Guidance, at 1–2). Mylan has represented that it meets the criteria set forth in the FDA CP Response. (*See* Ex. 50 – 2015.05.29 Mylan Conference Transcript, at 5; Ex. 51 – 2015.06.09 Mylan Conference Transcript, at 13). In the first step of Defendants' synthetic process for glatiramer acetate, "N-carboxyanhydrides of the amino acids alanine, glutamic acid, lysine, and tyrosine are combined with the initiator diethylamine to form long chains." (Ex. 58 – Order, *Teva Pharms. USA, Inc. et al. v. Sandoz, Inc., et al*., No. 1:08-cv-07611 (S.D.N.Y. June 29, 2012), ECF No. 336 at 79). Defendants use benzyl-protected glutamic acid and TFA-protected lysine as

starting materials for Step 1. *Id.* Defendants' Step 1 results in a copolymer retaining benzyl protecting groups on the glutamic acid residues and TFA protecting groups on the lysine residues, *i.e.*, a protected copolymer ("a first material"). (*See id.*).

167. Upon information and belief, Defendants' manufacturing process for the Mylan Glatiramer Acetate Products comprises "treating the first material to deprotect the benzyl-protected L-glutamic acid therein and to partially depolymerize the first material, thereby generating a second material." This step is also part of the fundamental glatiramer acetate synthetic scheme, (*see* Ex. 16 – FDA CP Response, at 13–14 and nn.44–46; Ex. 19 – FDA Draft Guidance, at 2), which Mylan has represented that it follows, (*see* Ex. 50 – 2015.05.29 Mylan Conference Transcript, at 5; Ex. 51 – 2015.06.09 Mylan Conference Transcript, at 13). In the second step of Defendants' synthetic process for glatiramer acetate, the protected copolymer is treated with HBr/acetic acid, removing the benzyl protecting groups and cleaving the polypeptide chains. (Ex. 58 – Order, *Teva Pharms. USA, Inc. et al. v. Sandoz, Inc., et al*., No. 1:08-cv-07611 (S.D.N.Y. June 29, 2012), ECF No. 336 at 80 ("[T]he addition of HBR/acetic acid serves two purposes. First, it removes the benzyl protecting groups from the glutamic acids. Second, it cleaves, or cuts, the polypeptide chains.")). The result of this step is a partially depolymerized copolymer retaining TFA protecting groups (*i.e.*, a "second material"). *Id*.

168. Upon information and belief, Defendants' manufacturing process for the Mylan Glatiramer Acetate Products comprises "treating the second material to deprotect the TFA-protected L-lysine to produce a third material." This step is also part of the fundamental glatiramer acetate synthetic scheme required by the FDA, (*see* Ex. 16 – FDA CP Response, at 13–14 & nn.44–46; Ex. 19 – FDA Draft Guidance, at 2), which Mylan has represented that it follows, (*see* Ex. 50 – 2015.05.29 Mylan Conference Transcript, at 5; Ex. 51 – 2015.06.09 Mylan Conference

Transcript, at 13). In the third step of Defendants' synthetic process for glatiramer acetate, the partially depolymerized copolymer is treated with piperidine to remove the TFA protecting groups from lysine residues. (Ex. 58 – Order, *Teva Pharms. USA, Inc. et al. v. Sandoz, Inc., et al*., No. 1:08-cv-07611 (S.D.N.Y. June 29, 2012), ECF No. 336 at 83–84 ("In Step 3 of Mylan's process, TFA-copolymer-1 is treated with piperidine, which removes the TFA protecting groups from the lysines.")). The result of this step is crude glatiramer acetate (*i.e.*, a "third material"). (*See id*; Ex. 16 – FDA CP Response, at 13–14 and nn.44–46).

169. Upon information and belief, Defendants' manufacturing process for the Mylan Glatiramer Acetate Products comprises "purifying the third material, to thereby produce the copolymer of L-glutamic acid, L-alanine, L-lysine, and L-tyrosine." The fourth step of Defendants' synthetic process for glatiramer acetate is purification by diafiltration using acetic acid. (Ex. 58 – Order, *Teva Pharms. USA, Inc. et al. v. Sandoz, Inc., et al*., No.1:08-cv-07611 (S.D.N.Y. June 29, 2012), ECF No. 336 at 84 ("In Step 4 of Mylan's process . . . the resulting product from Step 3 is purified by diafiltration using acetic acid.")). Upon information and belief, purification is a step that Defendants perform as part of commercial manufacture. As discussed above, the resulting Mylan Glatiramer Acetate Products are copolymers of L-glutamic acid, L-alanine, L-lysine, and L-tyrosine. (*See, e.g.*, Ex. 38 – Mylan 40mg Label, at 6; Ex. 39 – Mylan 20mg Label, at 6).

170. Upon information and belief, Defendants' manufacturing process for the Mylan Glatiramer Acetate Products comprises "measuring pyro-glutamate content of the copolymer in a sample of the copolymer." Pyro-glutamate is a process signature for glatiramer acetate synthesis because endo glutamic acid cyclizes to form pyro-glutamate under strong acid conditions resulting in cleavage such that pyro-glutamate becomes the "new" N terminus. (*See* Ex. 16 – FDA CP

Response, at 18 n.61, 28). The FDA confirms assessing termini is key to process control and evaluation during glatiramer acetate synthesis. (*See* Ex. 16 – FDA CP Response, at 28; Ex. 19 – FDA Draft Guidance, at 3). Specifically, comparison of "[s]tructural signatures for polymerization and depolymerization" of potential glatiramer acetate batches to Copaxone® (glatiramer acetate injection) batches, such as "the relative proportion of amino acids present at position 1 of the N-termini of glatiramer acetate," is one of the four criteria the FDA uses to establish active ingredient "sameness." (*See* Ex. 16 – FDA CP Response, at 21, 28). Mylan has represented that it meets the criteria set forth in the FDA CP Response. (*See* Ex. 50 – 2015.05.29 Mylan Conference Transcript, at 5; Ex. 51 – 2015.06.09 Mylan Conference Transcript, at 13). Mylan indeed represented that its ANDA included "rigorous side-by-side analyses, including characterization data, [demonstrating] that Mylan's Glatiramer Acetate Injection 20 mg/mL and 40 mg/mL have the same active ingredient" as Copaxone® (glatiramer acetate injection). (Ex. 25 – 2017.10.03 Mylan Press Release, at 1–2). In addition, measuring pyro-glutamate is essential to control batch-to-batch variability because pyro-glutamate is a critical process signature that allows a manufacturer to tell if the manufacturing process is working properly. (*See, e.g.*, Ex. 2 – '374 patent, at 9:26–10:11). Upon information and belief, Defendants thus at least measure the pyro-glutamate content of the glatiramer acetate in the Mylan Glatiramer Acetate Products as a quality control measure.

171. Upon information and belief, Defendants' manufacturing process for the Mylan Glatiramer Acetate Products comprises "measuring the peak average molecular weight (Mp) of the copolymer." The average molecular weight of the polypeptide chains is specified in the approved label for Mylan's 20 mg/mL and 40 mg/mL glatiramer acetate products. (*See* Ex. 38 – Mylan 40mg Label, at 6; Ex. 39 – Mylan 20mg Label, at 6). The fundamental reaction scheme for glatiramer acetate specified in the FDA CP response also contemplates controlling the

manufacturing process in order to obtain glatiramer acetate of a molecular weight within 5,000 to 9,000 Da. (*See* Ex. 16 – FDA CP Response, at 13 n.44). Mylan has represented that it follows this process. (*See* Ex. 50 – 2015.05.29 Mylan Conference Transcript, at 5; Ex. 51 – 2015.06.09 Mylan Conference Transcript, at 13). In addition, to be approved as a generic, Mylan would have had to show that its glatiramer acetate's molecular weight distribution matches that of Copaxone® (glatiramer acetate injection). (*See* Ex. 16 – FDA CP Response, at 23–24). Thus, since Mylan's Glatiramer Acetate Products have been approved as generic versions of Copaxone® (glatiramer acetate injection), upon information and belief, Defendants measure peak average molecular weight as part of the commercial manufacturing process.

172. Upon information and belief, the information generated by Defendants' measurements of the peak average molecular weight and pyro-glutamate content of their Mylan Glatiramer Acetate Products is routinely (*i.e.*, habitually, regularly, and repeatedly) recorded and retained. Upon information and belief, Defendants perform these quality control measurements as a part of their commercial production process for each batch of the Mylan Glatiramer Acetate Products that they manufacture.

173. Upon information and belief, Defendants' manufacturing process for the Mylan Glatiramer Acetate Products comprises "processing the copolymer to produce a pharmaceutical composition comprising glatiramer acetate only if the measured pyro-glutamate content of the copolymer in the sample is within 2000–7000 parts per million (ppm) on a dry weight/dry weight basis." The claimed pyro-glutamate range is representative of the distribution of pyro-glutamate across multiple lots of Copaxone® (glatiramer acetate injection). (*See* Ex. 2 – '374 Patent, at Example 5). According to Mylan, its ANDA included "rigorous side-by-side analyses, including characterization data, [demonstrating] that Mylan's Glatiramer Acetate Injection 20 mg/mL and

40 mg/mL have the same active ingredient" as Copaxone® (glatiramer acetate injection). (Ex. 25 – 2017.10.03 Mylan Press Release, at 1–2). In approving Mylan's Glatiramer Acetate Products, the FDA has authorized Mylan to commercialize only such products that are the same as Copaxone® (glatiramer acetate injection). Accordingly, upon information and belief, Defendants' manufacturing process ensures that the Mylan Glatiramer Acetate Products are prepared only from glatiramer acetate batches having pyro-glutamate within a range matching Copaxone® (glatiramer acetate injection), *i.e.*, within the claimed range. Upon information and belief, the Mylan Glatiramer Acetate Products are made only from glatiramer acetate having pyro-glutamate content within 2000–7000 parts per million (ppm) on a dry weight/dry weight basis.

174. Thus, upon information and belief, Defendants control and monitor the pyro-glutamate levels and peak average molecular weight as steps in the manufacturing process for Mylan's Glatiramer Acetate Products as claimed in the '374 patent, and "thereby produc[e] a pharmaceutical composition comprising glatiramer acetate."

175. Alternatively, to the extent the Mylan Glatiramer Acetate Products are not manufactured by a process that literally falls within the claims of the '374 patent, upon information and belief, the Mylan Glatiramer Acetate Products are manufactured by a method that performs substantially the same function in substantially the same way with substantially the same result as the methods claimed in the '374 patent. In addition, Defendants' Mylan Glatiramer Acetate Products are manufactured using a method that is insubstantially different from the methods claimed in the '374 patent. For example, like the methods claimed in the '374 patent, Defendants' manufacturing process for their Mylan Glatiramer Acetate Products ensures that those products are the same as the active ingredient in Copaxone®. (*See* Ex. 25 – 2017.10.03 Mylan Press Release,

at 1–2; Ex. 50 – 2015.05.29 Mylan Conference Transcript, at 5; Ex. 51 – 2015.06.09 Mylan Conference Transcript, at 13).

176. Upon information and belief, Mylan has had knowledge of and notice of the '374 patent and is knowingly and willfully infringing the '374 patent.

177. Mylan's conduct in infringing the '374 patent renders this case exceptional within the meaning of 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Momenta prays for judgment as follows:

A. That Mylan Pharmaceuticals, Inc., Mylan Inc., Viatris Inc., Mylan Teoranta, Natco Pharma Ltd., and Gland Pharma, Ltd. have infringed, are infringing, or will infringe, one or more claims of United States Patent No. 8,859,489;

B. That Mylan Pharmaceuticals, Inc., Mylan Inc., Viatris Inc., Mylan Teoranta, Natco Pharma Ltd., and Gland Pharma, Ltd. have infringed, are infringing, or will infringe, one or more claims of United States Patent No. 9,395,374;

C. That Mylan Pharmaceuticals, Inc., Mylan Inc., Viatris Inc., Mylan Teoranta, Natco Pharma Ltd., and Gland Pharma, Ltd., their officers, agents, and employees, and those persons in active concert or participation with any of them, and their successors and assigns, be permanently enjoined from infringement, inducing infringement, and contributory infringement of the patents-in-suit, including but not limited to the making, using, selling, and/or offering for sale in the United States, and/or importing into the United States, any devices, products, or methods that infringe the patents-in-suit before their respective expiration dates;

D. That infringement by Mylan Pharmaceuticals, Inc., Mylan Inc., Viatris Inc., Mylan Teoranta, Natco Pharma Ltd., and Gland Pharma, Ltd. is willful;

E. That Momenta be awarded all damages or other monetary relief adequate to compensate Momenta for Defendants' infringement of the patents-in-suit, such damages to be determined by a jury and, if necessary to adequately

compensate Momenta for the infringement, an accounting, and that such damages be trebled and awarded to Momenta with pre-judgment and post-judgment interest, but in no event less than a reasonable royalty;

F. That this case be declared an exceptional case within the meaning of 35 U.S.C. § 285 and that Momenta be awarded the attorney fees, costs, and expenses incurred in connection with this action; and

G. That Momenta be awarded such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff Momenta hereby demands a trial by jury on all issues so triable.

Dated: May 20, 2022

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ECKERT SEAMANS CHERIN & MELLOTT, LLC

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